STATE OF WEST VIRGINIA
DEPARTMENT OF HEALTH AND HUMAN RESOURCES
BUREAU FOR MEDICAL SERVICES

Office of Pharmacy Service
Prior Authorization Criteria

KUVAN® (sapropterin)
Prior Authorization Request Form

Kuvan is a phenylalanine hydroxylase activator indicated to reduce blood phenylalanine (Phe) levels in patients with hyperphenylalaninemia (HPA) due to tetrahydrobiopterin-(BH4)- responsive Phenylketonuria (PKU). Kuvan is to be used in conjunction with a Phe-restricted diet.

Criteria for Approval

1) Diagnosis of phenylketonuria; **AND**
2) Documentation that the patient is adhering to a Phe-restricted diet, and continues to have baseline PHE levels above 360 µmol/L; **AND**
3) Prescriber must submit patient's baseline weight and phenylalanine levels at initiation of therapy for a thirty (30) day supply. Initial dosing will be calculated for 10mg/kg/day; **AND**
4) Additional authorization of a thirty (30) day supply at a dose of 20mg/kg/day will be granted if patient does not respond adequately to initial dosing; **AND**
5) Re-authorization for one (1) six (6) month period will be issued with documentation of reduced phenylalanine levels within goal range (120-360 µmol/L) and documentation of patient compliance. Subsequent authorizations may be issued for up to twelve (12) months depending on patient compliance.
   Doses exceeding 20mg/kg/day will not be authorized.

References

1) Lexi-Comp Clinical Application 05/06/2015
2) Kuvan. Clinical Pharmacology. Tampa (FL): Gold Standard. Retrieved from http://clinicalpharmacology.com/Forms/search.aspx?s=kuvan on 4/20/2015.
3) Kuvan [package insert]. Novato, CA: BioMarin Pharmaceutical Inc.; 2014.
4) Vockley J, Andersson HC, Antshel KM, et al. "Phenylalanine Hydroxylase Deficiency: Diagnosis and Management Guideline" *ACMG Practice Guideline.* 2014. Accessed 4/20/2015.

Version 2 – created 05-06-2015 (BMT)
Approved by DUR Board 5/27/2015 (BMT)

v2015.2a